

583-252-0 FWC DIV



# 36

**IN THE UNITED STATES PATENT & TRADEMARK OFFICE**

IN RE APPLICATION OF:

MANFRED ASSMUS ET AL

: EXAMINER: SELLERS

SERIAL NO. 08/813,950

:

FILED: MARCH 3, 1997

: GROUP ART UNIT: 1712

FOR: THERMOPLASTIC COATING AND  
BINDING AGENT FOR MEDICINAL  
FORMS**SUPPLEMENTAL DECLARATION UNDER 37 C.F.R. §1.132**ASSISTANT COMMISSIONER FOR PATENTS  
WASHINGTON, D.C. 20231

SIR:

I, Manfred Assmus, declare and state as follows:

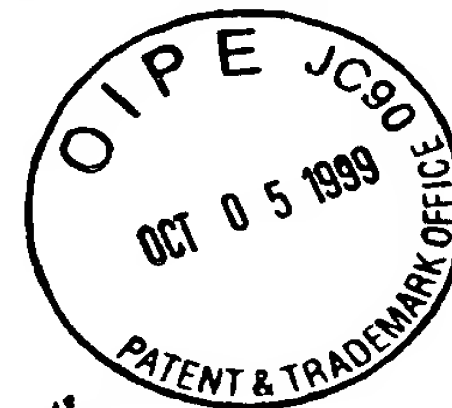
1. I am a coinventor of the above-identified application.
2. The following additional experiments were carried out by me and/or under my supervision and control.

**EXPERIMENTS**

EUDRAGIT RS PO polymer was mixed with 50 wt.% stearyl alcohol, stearic acid, PEG 6000 or with 50 or 80 wt.% glycerol monostearate (GMS).

The mixtures were heated to 65, 100 and 150°C. Samples of the mixtures were watched and photographed under a special melt-microscope (Schmelzmikroskop) in order to show the interaction of the flow improver and the polymer.

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## RESULTS

The results can be seen on the attached of photographs and are summarized in the Table below.

**TABLE**

	65°C	100°C	150°C
Steryl alcohol (50%)	-	+	++
Stearic acid (50%)	-	+	++
PEG 6000 (50%)	-	+	++
GMS (50%)	-	+	++
GMS (80%)	-	+	++

- = The polymer particles shown are irregularly shaped with sharp, rough surface. No interaction between the flow improver and the polymer.

+ = The polymer shape/surface is changing from rough to smooth. The interaction is beginning.

++ = The polymer shape/surface is very smooth. Strong interaction between flow improver and polymer.

### Conclusion:

None of the melts representative of the prior art mixed at 65°C were homogeneous. Temperatures under 100°C thus are not suitable for the purpose of the invention requiring claimed components A) and B) to be miscible in the melt so as to obtain a product as claimed.

As one skilled in this art, I consider the results obtained by the practice of the claimed invention to be unobvious and unexpected and of significant and material import.

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3. The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

4. Further, declarant saith not.

  
\_\_\_\_\_  
Manfred Assmus

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Date

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COPY

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I, Manfred Assmus, declare and state as follows:

1. I am a coinventor of the above-identified application.
2. The following experiments were carried out by me and/or my supervision and control.

EXPERIMENTS

Examples (under 100°C)

Procedure:

Eudragit® RS PO, a copolymer from 65 wt.% methyl methacrylate, 30 wt.% ethylacrylate and 5 wt.% 2-tri-methyl-ammoniumethylmethacrylate chloride, was mixed with 20, 30, 40, 50, 60, 70 and 80 wt.% glycerol-monostearate (GMS) for 30 min. in a blender and subsequently heated in an oven at 60, 65 und 80°C for 1 hour.

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**Results:**

- 1 = white powder, inhomogeneous  
 2 = white porous agglomerate, inhomogeneous  
 3 = white, opaque to homogeneous melt  
 4 = white, almost clear homogeneous melt

GMS wt. %	60°C	65°C	80°C
20	1	1	2
30	1	1	2
40	1	1	2
50	1	1	2
60	1	1	2
70	1	1	3
80	1	2	4

**Conclusion:**

None of the melts representative of the prior art was (absolutely) clear and homogeneous, optical clarity not being reached even at 80°C. Temperatures under 100°C thus are not suitable for the purpose of the invention requiring claimed components A) and B) to be miscible in the melt state recognizable by optical clarity of the melt (page 7, line 22, of the specification) so as to obtain a product as claimed.

As one skilled in this art, I consider the results obtained by the practice of the claimed invention to be unobvious and unexpected and of significant and material import.

3. The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false

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4. Further, declarant saith not.

Manfred Assmus  
Manfred Assmus

99-06-27  
Date

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